

REMARKS

Claims 1-9 and new claims 39-41 are currently pending in the application with claims 1 and 39 being in independent form.

Claim 1 has not been amended in this response. New claim 39 is being presented which clarifies that the collar is received between the annular skirt and the needle receiving port of the holder housing to form an interface fit via a groove/protrusion assembly between the annular skirt and the collar. New claims 40 and 41 correspond in subject matter with originally filed claims 5 and 6. Support for new claims 39-41 is provided in paragraph [0045] of the originally filed specification, the drawings, and originally filed claims 5 and 6.

No new matter has been added.

It is respectfully submitted that new claims 39-41 do not introduce new issues that require further search and/or consideration. The basis for claims 39-41 is provided in originally filed claim 5 upon which an examination has been completed. Originally filed claim 5 is directed to an interface fit via a protrusion on the collar cooperating with a groove in the annular skirt. Claim 39 merely clarifies the interface fit between the annular skirt and collar via a groove/protrusion assembly.

Response to Rejections

Claims 1-2, 5-6, and 9 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over United States Patent No. 5,277,311 to Hollister in view of United States Patent No. 4,982,842 to Hollister. Claims 3-4 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Hollister ('311) in view of Hollister ('842) and further in view of United States Patent No. 6,695,819 to Kobayashi. Claims 3-4 also stand finally rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Hollister ('311) in view of Hollister ('842) and further in view of United States Patent No. 6,440,104 to Newby et al. Further, claim 7 stands rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Hollister ('311) in view of Hollister ('842), Newby, and further in view of United States Patent Application Publication No. 2003/0028152 to Alesi et al. Claim 7 also stands rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Hollister ('311) in view of Hollister ('842), Kobayashi, and further in view of Alesi et al. Claim 8 stands rejected under 35 U.S.C. §103(a)

as allegedly being unpatentable over Hollister ('311) in view of Hollister ('842) and further in view of United States Patent No. 5,681,295 to Gyure et al. Each of these rejections is respectfully traversed for the reasons set forth herein.

The Office Action relies on Hollister ('311) as teaching a holder assembly comprising a holder housing (2) and a safety shield (20) pivotably attached to a collar (18) wherein the collar and safety shield are axially rotatable with respect to the holder housing. As discussed at column 3, lines 23-36 of Hollister ('311), the receptacle end (6) of the holder housing (2) includes a protuberance or boss (16) about which the collar (18) is fitted via an internal circumferential groove (22).

The Office Action acknowledges that Hollister ('311) fails to teach an annular skirt such that the collar can be received between the annular skirt and the needle receiving port of the holder housing.

The Office Action then relies upon the teachings of Hollister ('842) as disclosing a holder assembly having an annular skirt extending about a receiving port. The Office Action then asserts that it would have been obvious to provide the holder assembly of Hollister ('311) with an annular skirt such that the collar is received between the annular skirt and the receiving port of the holder housing as taught by Hollister ('842) in order to allow an annular protrusion on the collar to externally mate with a holder housing.

Applicant respectfully disagrees with this position for the following reasons. The combination of Hollister ('311) with Hollister ('842) fails to provide any suggestion to **(A)** provide an annular skirt; **(B)** to locate a mounting collar between an annular skirt and a needle receiving portion of the holder housing; and **(C)** redesign the relationship between the mounting collar and the holding housing to form an interfitting relationship of the collar with this annular skirt such that the shield can pivot with respect to the collar and the annular skirt.

As discussed briefly above, Hollister ('311) teaches that the collar (18) is mounted on the outer surface of the receptacle end (6) of the holder housing (2) via boss/protuberance (16). As such, in order to perform the combination suggested in the Office Action, a complete redesign of the holder housing would be required in Hollister ('311) in order to be able to locate the mounting collar between an annular skirt and a needle receiving port.

Hollister ('842) discloses at column 6, lines 62+ that the device relied upon in the rejection is a luer lock type syringe (72) comprising an internally threaded collar (76) surrounding its male luer (74). The mating of section (2b) to male luer (74), with the addition of annular collar (76), is achieved by extension (18) at the distal end of section (2b) which threadedly mates with thread (78) at the inner circumference of collar (76). As such, Hollister ('842) teaches a completely different device than that shown by Hollister ('311). One having ordinary skill in the art would not be motivated to look to the teachings of Hollister ('842), which is directed to a luer lock syringe system when modifying a needle holder assembly such as shown by Hollister ('311). Quite simply, Hollister ('842) teaches a skirt through collar (76), but such a skirt is to be used for an entirely different purpose, namely, to lock the needle to the syringe device. Such an interlocking engagement that locks the needle to the syringe is very different than the claimed arrangement, where the shield collar is adapted to be rotatable within the annular skirt. Furthermore, even if one *were* motivated to include the annular skirt of Hollister ('842) for the holder assembly of Hollister ('311), one would **not** be further motivated to redesign the interfitting relationship between the mounting collar and the holder housing so that the shield can pivot with respect to the collar and the annular skirt, where the collar is axially rotatable within the skirt as set forth in the claims.

New claim 39 further clarifies the invention in that it recites that the collar is received between the annular skirt and the needle receiving port of the holder housing to form an interface fit via a groove/protrusion assembly between the annular skirt and the collar.

The combination of Hollister ('311) with Hollister ('842) also fails to teach the features of originally filed claim 5 which recites that an outer surface of the collar includes a protrusion and an inner surface of the annular skirt includes a groove and that the groove on the annular skirt is adapted to receive the protrusion on the annular collar, thereby providing an interface fit when the collar is received between the annular skirt and the needle receiving port of the holder housing. The combination of references also fails to teach the features of claim 6, which depends from and further limits claim 5, which recites that the protrusion is annular and extends around the outer surface of the collar and the groove is annular and extends around the inner surface of the annular skirt.

With regard to the statement of the Office Action that the threads of the annular skirt of Hollister ('842) could be modified to include a boss and groove mechanism to allow rotation of the shield/collar assembly, Applicants respectfully disagree. As argued in the Response filed November 5, 2008, radial rotation of the safety shield and collar of Hollister ('842) about an axis of the holder housing would inevitably result in axial movement of the collar along the axis as extension (18) would travel along thread (78) in an axial direction. Hollister ('842) is a luer lock syringe, which is a completely different device than the holder assembly of Hollister ('311). Accordingly, Hollister ('842) would fail to provide any suggestion to "modify" the threads to include a boss and groove mechanism to allow for rotation of a shield/collar assembly and actually teaches away from any type of radial rotation during use due to the possibility of leakage occurring between the luer interface of male luer (74) and section (2b), thus rendering the device inoperable.

Accordingly, for the reasons set forth above, it is respectfully requested that the rejection of claims 1-2, 5-6, and 9 be withdrawn as the combination of Hollister ('311) with Hollister ('842) fails to render these claims obvious.

With respect to dependent claims 3-4, 7, and 8, none of the secondary references to Kobayshi, Newby et al., Alesi et al., or Gyure et al. overcome the deficiencies of the combination of Hollister ('311) with Hollister ('842).

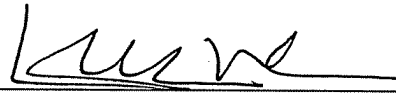
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CONCLUSION

In view of the arguments set forth above, the amendment to claim 1, and the addition of new claims 39-41, it is respectfully requested that this Amendment be entered and all claims in the application, namely claims 1-9 and 39-41, be allowed and the application passed to issue.

Respectfully submitted,
THE WEBB LAW FIRM

By



Kirk M. Miles
Registration No. 37891
Attorney for Applicant(s)
436 Seventh Avenue
700 Koppers Building
Pittsburgh, PA 15219
Telephone: (412) 471-8815
Facsimile: (412) 471-4094
E-mail: webblaw@webblaw.com